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09/772,790	01/30/2001	Endre Markovits Schersl	HAR-104	2203

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/772,790	Applicant(s) SCHERSL, ENDRE MARKOVITS	
	Examiner Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 37-69* is/are pending in the application.

4a) Of the above claim(s) *37-61 and 69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 62-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on November 24, 2003 wherein claims 1-5 have been amended and new claims "37-44" are added, and claim 36 is cancelled.

As recorded in the previous Office Action June 18, 2003, claims 37-61 drawn to a method for lowering LDL-cholesterol levels or for elevating HDL-cholesterol levels in blood of a mammal comprising the composition, withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, are still **pending** in this application. It is noted that new claim "44" is also drawn to a method for lowering cholesterol levels in blood of a mammal. Thus, new claim "44" will be withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Since applicant has two set of originally presented claims numbered "37-44", the new claims "37-44" herein have been renumbered in accordance with Rule 126 to claims 62-69. Thus, the claims herein are now numbered 1-35 and 37-69.

Currently, claims 1-35 and 37-69 are pending in this application. Claims 37-61 and 69 will be withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1-5 as amended now and new claims 62-68 are examined on the merits herein.

Abstract

As recorded in the previous Office Action June 18, 2003, the abstract of the disclosure is objected to because the instant abstract contains more than a single paragraph and exceeds 250 words. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details (emphasis added).

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

However, the instant Abstract has not been amended or corrected yet.

Applicant's amendment changing the limitation to "wherein the fatty acids are long chain fatty acids" in claims 1 filed on November 24, 2003 with respect to the rejection of claims 1-5 made under 35 U.S.C. 102(b) as being anticipated by Levin et al.

(US 3,031,376) for reasons of record stated in the Office Action dated June 18, 2003 have been considered and are found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

Applicant's amendment canceling claim 36 filed on November 24, 2003 with respect to the rejection of claim 36 made under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (US 3,031,376) in view of Granja et al. (US 5,663,156) and Hasegawa et al. further in view of Bundgaard (Book, "Design of prodrugs" Chapter 1, page 1) for reasons of record stated in the Office Action dated June 18, 2003 has been considered and is found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

The following is new rejection(s) necessitated by Applicant's amendment filed on November 24, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 62, 64, and 66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment, submitted November 24, 2003 with respect to amended claim 1 has been fully considered but is deemed to insert new matter into the claims, "wherein the fatty acids are long chain fatty acids", since the specification and claims as originally filed does not provide support for "wherein the fatty acids are long chain fatty acids". The original specification and claims merely discloses that fatty acid moiety of the esters is a carboxylic acid containing from 2 to 22 carbon atoms. One skilled in the art would recognize that long chain fatty acids could contain more than 22 carbons.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 as amended now and new claims 62-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "long" or the phrase "long chain" in claim 1 is a relative term which renders claims 1-5 and 62-68 indefinite. The term "long" is not defined in the

specification and claim. Therefore, the claims are indefinite as to the composition encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 62, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Miettinen et al. (US 5,502,045, PTO-892).

Miettinen et al. discloses a composition comprising fatty acid esters mixture such as a methyl ester mixture of fatty acids, wherein the acid moiety of esters is a fatty acid containing from 2 to 22 carbon (see particularly col.3 lines 64 to col.4 line 1; Example 1-5 at col.5-6). Miettinen et al. also discloses that the composition therein further comprises food as a carrier such as vegetable oils as a liquid carrier (see particularly Example 1-5 at col.5-6) is useful in reducing serum cholesterol level (see title and abstract).

Thus, Miettinen et al. anticipates claims 1, 62, and 66.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 as amended now and new claims 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasegawa et al. (of record) and Granja et al. (US 5,663,156, of record) and Levin et al. (US 3,031,376, of record) in view of Bundgaard (Book, "Design of prodrugs" Chapter 1, page 1, of record).

Hasegawa et al. discloses that the instant preferred fatty acid, linoleic acid, is known to have hypocholesteremic effect and lower the serum cholesterol levels, and therefore is useful in compositions (e.g., sunflower oil or vegetable oils known containing linoleic acid) for treating hypercholesterolemia (see the English Abstract in particular).

Granja et al. discloses that the instant preferred policosanols such as tetracosanol, hexacosanol, heptacosanol, octacosanol, and triacontanol are useful in compositions and methods for treating hypercholesterolemia and atherosclerosis (see abstract, Table 1-2 at col.3, Example 11-13 at col.12-14 and claims 1-20).

Levin et al. discloses a composition comprising one or more esters of tetracosanol, hexacosanol, octacosanol, and triacontanol, wherein the acid moiety of esters is a carboxylic acid containing from 2 to 22 carbon such as acetic acid (having 2 carbons) and propionic acid (having 3 carbons), (see particularly col.1 lines 13-17; col.3 lines 49-53 and 60-71; Example 3 at col.7 lines 19-26). Levin et al. also discloses that the composition therein further comprises food as a carrier such as vegetable oils as a

liquid carrier (see particularly col. 4 lines 10-12 and 34-38). Levin et al. also discloses that the composition therein further comprises corn starch and/or lactose (known excipients) and/or vitamins (known antioxidants) (see particularly col. 4 lines 19 and 22). Levin et al. further discloses that the composition herein to be administered to human mammals and animals is for reducing anoxia, improving physical endurance, reducing fatigue, and stimulating or improving heart response (see col.3 lines 53-57).

The above cited prior art do not expressly disclose the employment of the particular fatty acids of esters, such as linoleic acid and the alcohol moiety such as tetracosanol, hexacosanol, octacosanol, and triacontanol.

Bundgaard teaches that esters of actives are most common prodrugs since esters of actives containing hydroxyl and carboxyl groups (also known as hydroxyl group in an alcohol and carboxyl group in a carboxylic acid conjugated or esterified by an ester bond) are hydrolyzed within the body (in vivo) by cleaving the ester bond to regenerate the active drug substances (see the bottom paragraph at page 1).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular carboxylic acid such as the instant preferred fatty acid, linoleic acid, as acid moiety of esters of tetracosanol, hexacosanol, octacosanol, and triacontanol in the claimed composition herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular carboxylic acid such as the instant preferred fatty acid, linoleic acid, as the acid moiety of esters of the policosanol herein such as tetracosanol, hexacosanol, octacosanol, and triacontanol in the claimed

composition herein, since esters of tetracosanol, hexacosanol, octacosanol, and triacontanol having the acid moiety such as acetic acid and propionic acid are known to be useful in compositions to be administered for therapeutic purposes (e.g., stimulating or improving heart response) according to Levin et al. Moreover, the instant preferred policosanol such as tetracosanol, hexacosanol, octacosanol, or triacontanol is known to be useful in compositions for treating hypercholesterolemia according to Granja et al. A fatty acid such as the instant preferred fatty acid, linoleic acid, alone is also known to be useful in compositions for treating hypercholesterolemia according to Hasegawa et al.

Further, the esters herein having two moieties, the preferred policosanol and linoleic acid, would be hydrolyzed within the body (in vivo) by cleaving the ester bond to regenerate two active drugs, the policosanol and linoleic acid, in the body, based on the well known teachings of esters as prodrugs in pharmaceutical art according to Bundgaard.

Therefore, one of ordinary skill in the art would have reasonably expected that conjugating the policosanol such as tetracosanol, hexacosanol, octacosanol, or triacontanol with a fatty acid such as linoleic acid, into an ester in a composition to be administered, and the ester regenerating the policosanol and linoleic acid in the body after administration, both known useful for the same purpose, i.e., treating hypercholesterolemia, would improve the therapeutic effects for treating the same disorder, hypercholesterolemia, and/or would produce additive therapeutic effects in treating the same. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) regarding combination inventions. It is considered prima facie obvious to combine two active

composition components into a single composition to form a third composition useful for the very same purpose.

As discussed in the previous Office Action, it is well settled that "intended use" of a composition or product, e.g., "lowering cholesterol levels or a pharmaceutical composition", will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's arguments filed on November 24, 2003 with respect to the rejection of claim 36 made under 35 U.S.C. 103(a) made under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection above.

Additionally, Applicant's assertion that all of prior art quoted by the examiner lack significant features and are too remote from one another to be combined to conclude prima facie obvious, has been considered but is not found persuasive. It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form a third composition that is to be used for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

In the instant case, as discussed in the set forth 103(a) rejection above, the instant preferred policosanol such as tetracosanol, hexacosanol, octacosanol, or triacontanol is known to be useful in compositions for treating hypercholesterolemia

according to Granja et al. A fatty acid such as the instant preferred fatty acid, linoleic acid, alone is also known to be useful in compositions for treating hypercholesterolemia according to Hasegawa et al.

Further, the esters herein having two moieties, the preferred policosanol and linoleic acid, would be hydrolyzed within the body (in vivo) by cleaving the ester bond to regenerate two active drugs, the policosanol and linoleic acid, in the body, based on the well known teachings of esters as prodrugs in pharmaceutical art according to Bundgaard.

Therefore, one of ordinary skill in the art would have reasonably expected that conjugating the policosanol such as tetracosanol, hexacosanol, octacosanol, or triacontanol with a fatty acid such as linoleic acid, into an ester in a composition to be administered, and the ester regenerating the policosanol and linoleic acid in the body after administration, both known useful for the same purpose, i.e., treating hypercholesterolemia, would improve the therapeutic effects for treating the same disorder, hypercholesterolemia, and/or would produce additive therapeutic effects in treating the same, absent evidence to the contrary. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) regarding combination inventions. It is considered prima facie obvious to combine two active composition components into a single composition to form a third composition useful for the very same purpose.

Applicant's working Examples 1-5 of the specification at pages 8-11 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art. Examples 1-5 provide no

clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since there is no side-by-side comparison with the closest prior art. Moreover, it is noted that the polycosanol esters or phytoserol-PUFA tested in Example 1-5 herein are not the particular fatty acids esters with the particular alcohol moiety as the instantly claimed. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention. See MPEP § 716.02(d). Therefore, the evidence presented in specification herein is not seen to be clear and convincing in support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
January 27, 2004

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

2/2/04